ZO SKIN HEALTH PIGMENT CONTROL CREME HYDROQUINONE-hydroquinone lotion
ZO Skin Health, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ZO ® Skin Health Pigment Control Creme 2% Hydroquinone
National Drug Code 42851-038-80

Drug Facts

Active Ingredient

Hydroquinone, 2%

Purpose

Skin Bleaching Agent

Uses

For the gradual fading of (or lightens) dark (or brownish) discolorations in the skin such as freckles, age spots, pigments in the skin that may occur in pregnancy or from the use of oral contraceptives.

Warnings

For external use only.

Avoid contact with eyes.

Do not use on children under 12 years of age unless directed by a doctor.

Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.

Keep out of reach of children.

If swallowed, seek medical help or contact a Poison Control Center right away.

Directions

- **Adults:** apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin.
- Children under 12 years of age: do not use unless directed by a doctor.
- Sun exposure should be limited by using a sunscreen agent or protective clothing to

cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Other Information

- Store at a controlled room temperature: 15°-30°C (59°-86°F), away from direct sunlight.

Inactive Ingredients

Aqua/Water/Eau, Ascorbic Acid, Ascorbyl Palmitate, Beta-Glucan, Caprylyl Glycol, Cetyl Alcohol, Chlorphenesin, Dioscorea Villosa (Wild Yam) Root Extract, Disodium EDTA, Glycerin, Glycolic Acid, Phenoxyethanol, Quillaja Saponaria Bark Extract, Smilax Aristolochiifolia Root Extract, Sodium Hydroxide, Sodium Lauryl Sulfate, Sodium Metabisulfite, Sodium Sulfite, Stearyl Alcohol, Tocopheryl Acetate, Yucca Schidigera Root Extract.

Questions?

5 Technology Dr. Irvine, CA 92618

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - 80 mL Bottle Carton

ZO ® SKIN HEALTH
BY ZEIN OBAGI MD

NDC 42851-038-80

PIGMENT CONTROL
CRÈME
2% Hydroquinone

80 mL / 2.7 Fl. Oz. U.S.

BRIGHTENING

ZO® SKIN HEALTH
BY ZEIN OBAGI MD

NDC 42851-038-80

PIGMENT CONTROL
CRÈME
2% Hydroquinone

80 mL / 2.7 Fl. Oz. U.S.

Dist. by ZO Skin Health, Inc. Irvine, CA 92618
Made in USA with US & Imported materials
zoskinhealth.com | 915100

2% hydroquinone crème lessens the appearance of discoloration for a more even skin tone.

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Drug Facts (continued)

Phenoxyethanol, Quillaja Saponaria Bark Extract, Smilax Aristolochiifolia Root Extract, Sodium Hydroxide, Sodium Lauryl Sulfate, Sodium Metabisulfite, Sodium Sulfite, Stearyl Alcohol, Tocopheryl Acetate, Yucca Schidigera Root Extract.

Questions?
5 Technology Dr. Irvine, CA 92618

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ZO SKIN HEALTH PIGMENT CONTROL CREME HYDROQUINONE

hydroquinone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42851-038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-038-80	1 in 1 CARTON	11/07/2018	09/23/2020

1		80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	11/07/2018	

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 4/2022 ZO Skin Health, Inc.